

REMARKS/ARGUMENTS

With entry of this amendment, claims 72-149 are pending. Claims 124-126, 131-133, 135-139, and 141-142 are allowed. Claim 128-130 are objected to as being dependent on a rejected base claim but would be allowable if rewritten in independent form. Claims 72, 83, and 85 have been amended as set forth in detail below. New claims 143-149 have been added. No new matter is added by these amendments. Examination and reconsideration of all pending claims are respectfully requested.

Interview Summary

Applicants thank the Examiner for the teleconference of December 14, 2004 with Craig Wong (Reg. No. 45,231) and the undersigned, during which the present objections to independent claims 72 and 102 were discussed. Also discussed was the present objection to claim 85 as well as the new matter objection to certain amendments in the specification. No agreement was reached during the interview.

With regard to the Examiner's Interview Summary dated December 17, 2004, Applicants may file a response to the Examiner's remarks contained therein at a later date.

Amendments to the Specification

The Examiner has objected to the disclosure due to the inclusion of "related applications" on page 1, lines 4-14. To make it clear that the present application is not a continuation application or continuation-in-part application of the referenced applications, Applicants herein delete the heading "Related Applications." Hence, the listing of the applications should merely list the applications without the heading. If the Examiner prefers that Applicants provide the list in another section of the patent application, Applicants respectfully request the Examiner's preference for the listing of the applications.

The Examiner has requested that Applicants fill in the three blank spaces for the serial numbers of the applications referenced on page 1, lines 4-14. To expedite prosecution of the present application, Applicants are providing the information. All of the referenced applications are currently pending, and none has issued or been abandoned. Applicants further submit as **Exhibit A**, a copy of the first page of the amendment that was filed on June 14, 2002.

In regards to the objection to Figure 5, in the response filed on April 5, 2004, Applicants submitted an amended Figure 5 which added label "Detail A." For ease of reference, Applicants include an additional copy of the marked up and clean copy of amended Figure 5.

New Matter Objection under 35 U.S.C. § 132

The Examiner believes the insertion of the application serial numbers in the amendment filed April 5, 2004, to constitute new matter under 35 U.S.C. § 132. The Examiner states that "the original specification did not contain any other information on these particular applications (i.e., title, attorney docket number, filing date, etc.)." Applicants respectfully disagree.

The serial numbers inserted into the specification in the amendment filed April 5, 2004, correspond exactly to the patent applications referenced on page 1, lines 4-14, of the specification as originally filed. Since each patent applications referenced on page 1, lines 1-14, is identified by its title, inventor, and filing date (stating "filed on even date herewith," *see* page 1, lines 11 and 12), the insertion of these serial numbers is not new matter. Consequently, entry of the serial numbers into the specification in the amendment of April 5, 2004, is also not new matter to the original specification under 35 U.S.C. § 132.

Claim Objections

Claims 83, 85, 135, 136, 141, and 142 are objected to because of alleged informalities.

Applicants have amended claim 83 to delete the term "is" that precedes "projects."

In regards to claim 85, Applicants have amended the claim to recite "wherein the barb(s) are integrally formed as part of the at least one strut." Because claim 74, on which claim 85 depends, recites "wherein at least one of the n struts comprises a barb," such a claim would encompass one or more barbs. Accordingly, it is respectfully submitted that there is proper antecedent basis for "barb(s)" (*i.e.*, at least one barb) in claim 85.

In regards to claims 135, 136, 141 and 142, all of which recite "one or more barbs," Applicants submit that such claims have proper antecedent basis as originally filed. All of the claims depend from independent claim 124. Because claim 124 defines the barbs as "integrally formed on every other strut in the second portion" (emphasis provided) and that the second portion comprises a serpentine ring that comprises "n interconnected struts," claim 124 would encompass one barb where $n = 2$, *i.e.*, where there are 2 struts in second portion. Further, claim 124 would encompass more than one barb where $n \geq 4$. Accordingly, the skilled artisan reading the claims in light of the specification would understand that there is proper antecedent basis for the phrase "one or more barbs" in claims 135, 136, 141, and 142.

In view of the above remarks and amendments, it is respectfully submitted that claims 83, 85, 135, 136, 141, and 142 are clear.

Information Disclosure Statement

Applicants submit herewith a Supplemental Information Disclosure Statement that includes the references that were not initialed by the Examiner. Applicants have not submitted the IDS electronically because the number of US patent documents cited exceeds the

maximum of 50 patents which may be cited per IDS submission that is filed electronically. Applicants have provided a CD-R which includes PDF copies of the US patent documents as well as the foreign patent documents cited in the IDS. Paper copies of the foreign patent documents and non patent literature documents have also been provided with the IDS. Applicants respectfully request that the Examiner initial the submitted references and that the references appear on the "References Cited" portion of any patent that issues from the present application.

Claim Rejections under 35 U.S.C. § 112, first paragraph

Claims 81, 82, 84, 89, 127, 134 and 140 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. Such rejections are traversed as follows.

In regards to claim 81, which recites that "the struts have a maximum strut width at the proximal apices or distal apices and a minimum strut width between the proximal apices and the distal apices," Applicants refer the Examiner to Figures 12 and 13 and page 48, line 1 to page 50, line 3 which provides written description support for claim 81.

In regards to claims 82 and 134, which recite "a ratio of the maximum strut width to minimum strut width is between about 1:1 and about 10:1", Applicants refer the Examiner to page 48, lines 7-10 and page 49, lines 17-20 which states that taper ratios from "1 to about 10 or greater are within the scope of the present invention."

In regards to claim 84, which recites "at least one barb projects at an azimuth angle relative to the longitudinal axis of the strut between about 5 to about 70 degrees so that the barb is laterally biased in a plane that is tangent to an outside surface of the strut," Applicants refer the Examiner to Figures 1A and 1B and page 26, line 21 to page 27, line 16 which provides written description support for claim 84.

In regards to claim 89, which recites "the connector member comprises a serpentine ring that comprises n apices," Applicants refer the Examiner to page 34, line 22, bridging to page 35, line 2, which provides written description support for claim 89.

In regards to claim 127, which recites "the serpentine ring connector member comprises $2n$ interconnected struts that define n proximal apices and n distal apices," it is respectfully submitted that the skilled artisan reading the specification would understand that n apices a serpentine ring are defined by $2n$ interconnected struts. Accordingly, Applicants refer the Examiner to page 34, line 22, bridging to page 35, line 2, which provides written description support for claim 127.

In regards to claim 140, which recites that "the circular radii of curvature comprise center points that are offset," Applicants refer the Examiner to Figures 10 and 11 and page 46, lines 3-14 which provide support for claim 140.

Claim Rejections under 35 U.S.C. § 102(b)

Kanesaka

Claims 72, 73, 80, 86-90, 94, 96, 99, and 100 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Kanesaka *et al.* (U.S. Patent No. 5,911,754, hereinafter "Kanesaka"). The Examiner contends that "Kanesaka anticipates the claim language where the first portion as claimed is met by the small mesh portion (3) ... which has 8 apices, the second portion as claimed is met by the large mesh portion (2) ... which has 4 apices, and the connectors as claimed are met by the connectors (5)." The present rejection is traversed in part and overcome in part as set forth below.

Amended claim 72 recites, *inter alia*, "cantilevered connector elements ~~integrally formed with~~ that extend distally from the n distal apices of the first portion." Support for this amendment is found in the specification at, *e.g.*, Figure 4, which shows a stent of the present

invention having connector elements 72 that are cantilevered and extend distally from the apices of region 90.

In contrast, Kanesaka discloses S-shaped "connectors" that connect apices of adjacent mesh portions of the stent. (*See, e.g.*, Figures 1-4 and col. 3, line 58, to col. 4, line 7.) Kanesaka does not show connectors that are cantilevered as presently recited in claim 72. Accordingly, Kanesaka does not anticipate claim 72, nor any claim depending therefrom.

Furthermore, in addition to the reasons discussed above, it is respectfully submitted that claims 80, 86, 88, and 90 are novel over Kanesaka for the reasons set forth below.

Claim 80 recites, *inter alia*, "wherein a width of the struts are tapered between the proximal apices and the distal apices." Claim 88 recites the stent of claim 72 "wherein the n connector elements are configured to be coupled to connector elements of a connector member." Claim 90 recites the stent of claim 72 "wherein the connector elements comprise opposing shoulder portions at a proximal end and a distal end." The Examiner has not shown where Kanesaka discloses these limitations as recited in claims 80, 88, and 90.

Claim 86 recites, *inter alia*, "wherein the outer diameters of the radially expandable stent varies along the length." The Examiner contends that the diameter "would inherently vary somewhat because of manufacturing imperfections," and that "the diameter would vary depending upon how the stent was expanded which could be done in segments."

Applicants respectfully submit that the Examiner's construction of claim 86 is unreasonable. The Examiner essentially construes the limitation recited in claim 86 -- variation of the outer diameters of the radially expandable stent -- as being any variation in stent diameter, irrespective of degree or significance, that might result from a manufacturing imperfection. The skilled artisan reading the above disclosure would not construe the recited variation in stent diameter as being met by insignificant variations resulting from manufacturing imperfections. Applicants believe that "manufacturing imperfections" are an insufficient basis for inherent anticipation of such a feature.

Further, with regard to the Examiner's comments that "the diameter would vary depending upon how the stent was expanded which could be done in segments," Applicants note that the Examiner is impermissibly supplementing the disclosure of Kanesaka to achieve the claimed invention. If the Examiner wishes to rely on principles of inherency to establish Kanesaka as anticipatory under 35 U.S.C. § 102, which requires that all elements or limitations be expressly or inherently disclosed by a single reference, then the Examiner is required to present evidence or technical reasoning that the allegedly inherent characteristic necessarily flows from the teachings of the applied reference. See MPEP § 2112. In this case, nowhere does Kanesaka disclose expanding the stent in segments. Accordingly, the Examiner cannot reasonably assert, as inherently disclosed in Kanesaka, any characteristic that would "necessarily" flow from expansion of the stent in segments.

For the reasons set forth above, Applicants believe that claims 72, 73, 80, 86-90, 94, 96, 99, and 100 as currently pending are not anticipated by Kanesaka.

Marin

Claims 102, 103, 106-108, 111-115, and 122-123 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Marin (U.S. Patent No. 5,397,355). The Examiner contends that Marin anticipates the claim language where "the barbs as claimed are the barb (18) of Marin, and the tuck pads as claimed are the collinear barbs [sic] (16) and ribs (14) that hold and conceal the barb prior to deployment." The instant rejection is traversed as set forth below.

Marin does not disclose a tuck pad configured to retain the barb when the stent is in a delivery configuration. Marin discloses a stent having circumferential ribs (14), bars (16) perpendicular to the ribs and which are collinear with the axis of the stent, and rectangular openings (12), each opening having sides defined by the two ribs and 2 bars. From each rib extends a barb (18). When in a delivery configuration, the barb extends into the opening (12). While the barb is positioned within the opening of Marin, it is not retained within the opening by a tuck pad as presently recited in the claims. In this regard, Applicants respectfully refer the

Examiner to Figure 4 of the present application, which shows one embodiment of a tuck pad (86) as recited in claim 102.

For the reasons set forth above, Marin does not anticipate claim 102 nor any claim depending therefrom.

Furthermore, Applicants respectfully note that the Examiner has not shown where Marin discloses the limitations recited in dependent claims 103, 106-108, 111-115, 122, and 123. Therefore, in addition to the reasons discussed above, it is submitted that claims 103, 106-108, 111-115, 122, and 123 are novel over the cited art with respect to the particular subject matter recited in these claims.

Claim Rejections under 35 U.S.C. § 103

Kanesaka (alone or in combination)

Claims 74-79, 81-85, 91-93, 95, 97, 98, and 101 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Kaneshaka, alone or in combination, as follows:

claims 74, 75, 78, 79, 83-85, 92, and 93 -- Kaneshaka in view of
Goicoechea *et al.* (U.S. Patent No. 5,800,508) (hereinafter
"Goicoechea");

claim 91 -- Kaneshaka in view of Wu *et al.* (U.S. Patent No.
6,254,632, hereinafter "Wu");

claims 81, 82, 95, 97, 98, and 101 -- Kaneshaka alone; and

claims 76 and 77 -- Kaneshaka in view of Goicoechea and in further
view of Marin.

These rejections are traversed in part and overcome in part as set forth below.

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103, the Examiner must show, *inter alia*, a teaching or suggestion of all claim limitations in the prior art. *See, e.g.*, MPEP §§ 2142 and 2143.03. It is respectfully submitted that neither Kanesaka, Goicoechea, Wu, nor Marin teach or suggest "cantilevered connector elements that extend distally from the n distal apices of the first portion," as presently recited in independent claim 72, from which claims 74-79, 81-85, 91-93, 95, 97, 98, and 101 depend. Accordingly, at least for this reason, claims 74-79, 81-85, 91-93, 95, 97, 98, and 101 are patentable over Kanesaka, either alone or in combination with Goicoechea, Wu, or Goicoechea in further combination with Marin.

Marin

Claims 104, 105, and 116-121 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Marin alone. Applicants respectfully traverse.

As noted above, a *prima facie* case of obviousness under 35 U.S.C. § 103 requires that the Examiner show, *inter alia*, a teaching or suggestion of all claim limitations in the prior art. *See, e.g.*, MPEP §§ 2142 and 2143.03. For the reasons set forth previously in response to the rejections in view of Marin under 35 U.S.C. § 102(b), Marin does not teach or suggest "one or more tuck pads configured to retain the one or more barbs when the radially expandable stent is in a delivery configuration," as recited in independent claim 102. Accordingly, it is submitted that claims 104, 105, and 116-121, which depend from claim 102, are not obvious in view of Marin.

Allowable Subject Matter

Claim 128-130 are objected to as being dependent upon a rejected base claim, but are indicated as allowable if rewritten in independent form. Applicants note that claims 128-130 each depend directly or indirectly from claim 124, which the Examiner has indicated as allowable. It is further submitted that claims 128-130 depend from an allowable base claim for

the reasons set forth above in response to the rejections under 35 U.S.C. §§ 102 and 103. Accordingly, claims 128-130 should be allowable as currently presented in dependent form.

Applicants appreciate the Examiner's indication of claims 124-126, 131-133, 135-139, 141, and 142 as allowed over the prior art of record.

New Claims

To further claim novel aspects of the present invention, Applicants have added new claims 143-149.

New dependent claims 143-147 recite specific embodiments of the radially expandable stent of claim 72. Support for these claims is found in the specification at, *e.g.*, Figures 4 to 6.

New independent claim 148 recites a "radially expandable stent comprising: a first portion that comprises a serpentine ring that defines n proximal apices and n distal apices; a second portion that comprises a serpentine ring that defines $n/2$ proximal apices and $n/2$ distal apices; and connector elements, each connector element having a proximal end and a distal end, wherein the proximal ends are integrally formed with the n distal apices of the first portion and the distal ends define a distal end of the radially expandable stent." New dependent claim 149 recites one specific embodiment of the stent of claim 148 "wherein the n connector elements are non-integrally coupled to connector elements of a connector member." Support for these claims is found in the specification at, *e.g.*, page 6, lines 1-3, page 11, line 6; and Figures 4 to 6.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 206-467-9600.

Respectfully submitted,

Dated: December 23, 2004

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: CHOBOTOV, et al.
Serial No.: 10/029,559
Conf. No.: 4960
Filed: December 20, 2001
For: *ADVANCED ENDOVASCULAR
GRAFT*
Art Unit: 3738
Examiner: Unassigned

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PRELIMINARY AMENDMENT

US Patent and Trademark Office
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Dear Sir:

In advance of the first examination in this case, Applicants request
amendment of the subject application, as follows (a marked up copy of the amended
specification is attached to this Amendment):

IN THE RELATED APPLICATIONS

Please replace the paragraph on page 1, lines 4 - 13, with the following:

This application is related to U.S. Patent Application Serial No.
10/029,570 entitled "Method and Apparatus for Shape Forming Endovascular Graft
Material" by Chobotov et al., U.S. Patent Application Serial No. 10/029,584 entitled
"Endovascular Graft Joint and Method for Manufacture" by Chobotov et al., U.S.
Patent Application Serial No. 10/029,557 entitled "Method and Apparatus for
Manufacturing an Endovascular Graft Section", by Chobotov et al. All of the above